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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KOSAR, ANDREW D	
ART UNIT	**PAPER NUMBER**
1654	

MAIL DATE	DELIVERY MODE
07/01/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,028	LIU ET AL.	
	Examiner	Art Unit	
	Andrew D. Kosar	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/28/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Notice to Comply/RAW seq. listing*.

DETAILED ACTION

Translation of Documents

The examiner requests clarification for the record on the following matter. This Application is a national stage entry of PCT/CN2002/00660, which claims priority to CN 02136688.8. There is a single English disclosure provided, however it indicates at the top of every page that it is the English translation of CN 02136688.8, and not the translation of PCT/CN2002/00660.

In the interest of compact prosecution, the examiner has assumed that the priority document is the same exact disclosure as the PCT, and that a translation of one is the translation of the other.

Applicant should clarify this discrepancy in response to this action.

Election/Restriction

Applicant's election of huOGP (claim 3) in the reply filed on March 4, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The restriction is still deemed proper and made FINAL.

Claim 11 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention/species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on March 4, 2008.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). A

computer readable form (CRF) of the sequence listing was submitted. However, the CRF could not be processed by the Scientific and Technical Information Center (STIC) for the reason(s) set forth on the attached CRF Diskette Problem Report.

To effect a complete response to this Office Action, Applicant must comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for reply beyond the SIX MONTH statutory period. Direct the reply to the undersigned. Applicant is requested to return a copy of the attached CRF Diskette Problem Report with the reply.

Claim Rejections - 35 USC § 112

> The following is a quotation of the second paragraph of 35 U.S.C. 112:
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the amount in the composition in (compound amount/body weight), however this is indefinite, as the claim is not drawn to a method, and thus one does not have sufficient understanding of the patient to know how much compound is in the composition. As the claim currently recites, the dose is relative to the body weight of the subject, however it is unclear as to what the amount of compound in the composition is without the definition of the subject. For example, in considering the dose of OGP only, if the patient is 10 kg, the dose

grange for OGP is 1 μg to 1 g, while for a 100 kg patient the range extends to 10 μg to 10 g. One is not reasonably apprised of the composition claimed, as the patient is of an undefined weight.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over JEFFERIES (US Patent 5,948,426) and RODAN (US Patent 5,461,034).

Jefferies teaches that, "Examples of growth factors that are suitable for the expansion of hematopoietic tissue in the collagen-DFDBA conjugate composites of the present invention include, but are not limited to, interleukin-4, interleukin-6, interleukin-7, platelet-derived growth factor, alpha interferon species, tumor necrosis factor (TNF), TGF-beta and TNF-alpha proteins, colony-stimulating factors, such as granulocyte colony-stimulating factor, stem cell proliferation factor, osteogenic growth polypeptide, autocrine growth factor, and the like, and their combinations." (column 6, lines 17-26).

Jefferies further provides various compositions and means of delivery as well as making the pharmaceutical compositions (e.g gel, powder, lyophilized sponge, combinations thereof, lyophilized sponge reground and reconstituted in pharmaceutical carrier- column 5, lines 12-65).

Rodan teaches the peptide ALKRQGRTKYGFGG (abstract) which is instant SEQ ID NO:1. Rodan teaches that this peptide is, "likely to enhance the hemopoietic microenvironment and consequently stimulate hemopoiesis at the noncommitted stem cell level avoiding the stem cell depiction and white cell discrimination." (column 3, lines 33-38) and teaches pharmaceutical compositions and methods of use to stimulate hematopoietic reconstruction (e.g. claims 16-19).

Rodan additionally teaches that, "The currently available clinical (experimental) treatment for stimulating post BMT marrow reconstruction consists mainly of the administration of recombinant human granulocyte colony stimulating factor (rhG-CSF) and/or recombinant human granulocyte-macrophage colony stimulating factor (rhGM-CSF) [Blazar R. B., et al. (1989) Blood 74:2264]. These cytokines affect directly the proliferation of transplanted pluripotent cells already committed to the white-cell lineages [Vellenga E., et al. (1987) Leukemia 1:584] and consequently decrease the time to leukocyte and neutrophil recovery." (column 2, line 40-50).

As set forth in *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980), "It is *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; the idea of combining them flows logically from their having been individually taught in prior art."

Here, the OGP, G-CSF and GM-CSF are all known for the very same purpose of bone marrow reconstruction, thus it would have been obvious to have combined the components into a composition for the very same purpose with the expectation that it would function to facilitate bone marrow reconstruction.

With regards to the form, e.g. lyophilized or in solution, both references teach various pharmaceutical compositions, and selection of a desired form is well within the purview of the artisan to determine which form is desired, each being equally identified as capable of being used for practicing the methods of Jefferies and Rodan.

Further, although Jefferies and Rodan do not teach a method of using a composition comprising the specifically claimed concentration of the compounds for OGP and G-CSF, absent evidence to the contrary, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have optimized the concentration for both components. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller,* 220 F.2d 454, 456, 105 USPQ 233, 235.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 08:00 - 16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew D Kosar/
Primary Examiner, Art Unit 1654